IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IDENIX PHARMACEUTICALS LLC and UNIVERSITA DEGLI STUDI DI CAGLIARI, Plaintiffs, v. GILEAD SCIENCES, INC., Defendant.	C.A. No. 14-846-LPS

OPENING BRIEF IN SUPPORT OF GILEAD'S MOTION FOR JMOL, NEW TRIAL, REMITTITUR, AND SEVERANCE/STAY OF ONGOING ROYALTY PROCEEDINGS

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TABLE OF CONTENTS

Page

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Page(s)

Page(s)

Other Authorities

NATURE AND STAGE OF THE PROCEEDING

In opposition to Gilead's *Daubert* and summary judgment motions, Idenix told this Court it would present evidence at trial sufficient to sustain a verdict of liability and $2.54 billion in damages. Idenix did not keep its promise. Instead, Idenix presented testimony that was legally insufficient to meet either the enablement or written description requirements, or to sustain a damages verdict. In moving the Court to set aside this verdict, Gilead is mindful that the Court may not reweigh the evidence admitted at trial. Rather, Gilead respectfully submits that the record, with all inferences drawn in Idenix's favor, compels a ruling that the '597 patent is invalid as a matter of law and that the jury's damages verdict cannot be sustained.

SUMMARY OF THE ARGUMENT

1. Idenix's experts testified that the '597 patent is enabled because it teaches the use of assays to screen "a lot of compounds" to find the active ones: "We use the screening because that is a way you actually cut down the number of compounds, by removing all the inactive ones." Tr. 1970:19-21 (De Francesco). In *Wyeth v. Abbott Labs.*, 720 F.3d 1380 (Fed. Cir. 2013), the Federal Circuit held that, when a patent requires screening of "a lot of compounds," Tr. 1918:11 (Meier), to discover the active ones, the claims lack enablement as a matter of law. A mere research plan is not an invention.

2. Idenix's witnesses testified that the specification does not disclose, and that until 2005 Idenix repeatedly failed to make and test, the 2' methyl up, 2' fluorine down set of compounds that are part of the scope of the claims as construed. This renders the claims invalid for non-enablement as a matter of law. *See, e.g., Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371 (Fed. Cir. 2007).

3. At Idenix's urging, and after considering statements made by Idenix during prosecution, the Court construed the claims to encompass all compounds with **any** "non-hydrogen substituents at the 2' down and 3' down positions." Prosecution statements cannot supply written description, as they postdate the priority date. The specification discloses a defined list of substituents at 2' down

that is narrower than the Court's construction, which reads on an **open-ended** set of any substituent but hydrogen (H) at this location. Because the disclosure in the specification is narrower than the claims as construed, the claims are invalid under *Ariad Pharms., Inc.* v. *Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (*en banc*).

4. Finally, Idenix made promises to the Court regarding its damages theory that it did not keep. First, Idenix proffered that its expert Mr. Carter would lay a foundation that the two agreements he relied on were technically and economically comparable to the hypothetical license. Second, Idenix claimed it would establish that the Entire Market Value Rule is satisfied. At trial, Mr. Carter abandoned any pretense of meeting either requirement. Each failure requires JMOL on damages.

STATEMENT OF FACTS

This JMOL motion is predicated on the evidence that Idenix and its experts presented to the jury, with all inferences drawn in Idenix's favor. The relevant facts are discussed below.

ARGUMENT

This Court has noted that JMOL is granted if "viewing the evidence in the light most favorable to the non-movant and giving it the advantage of every fair and reasonable inference," a verdict cannot be sustained due to an absence of substantial evidence or a legal defect. *Ateliers De La Haute-Garonne v. Broete Automation-USA, Inc.*, 85 F. Supp. 3d 768, 774-75 (D. Del. 2015) (Stark, J.).

In particular, JMOL should be granted when the testimony of the prevailing parties' expert does not meet the legal standards in Federal Circuit precedent. *Genentech, Inc. v. Wellcome Found. Ltd.*, 29 F.3d 1555, 1569 (Fed. Cir. 1994) (reversing a jury finding of infringement and a denial of JMOL based on testimony of prevailing parties' expert). Gilead respectfully submits that the testimony of Idenix's witnesses, fully credited by the jury, necessitates the grant of this JMOL motion.

I. CREDITING ALL FACTS IN IDENIX'S FAVOR, THE '597 PATENT DOES NOT ENABLE THE FULL SCOPE OF ITS CLAIMS AS A MATTER OF LAW

Enablement is a question of law for this Court to decide. *Wyeth*, 720 F.3d at 1384. As

construed, the claims recite a method for treating HCV by administering compounds having two key features: (1) The claims recite a ß-D-nucleoside with a five-membered sugar ring having, among other features, a methyl group in the 2' up position and *any* substituent other than hydrogen at the 2' and 3' down positions ("structural limitations"); (2) the claimed compounds are limited to those that are effective to treat HCV. *See* D.I. 237; D.I. 238 at 12; D.I. 431 at 10-12; Tr. 1851:8-13 (Meier).

Idenix's testimony established that the '597 patent fails to enable the full scope of its claims, for at least two reasons. **First**, Idenix's experts testified that: (a) "a lot of compounds" are covered by the claimed structural limitations; (b) a "significantly smaller" number of those compounds are effective to treat HCV; and (c) the effective compounds are discovered via screening. The Federal Circuit has held that required screening of "a lot of compounds," Tr. 1918:11 (Meier), to find the active species fails to enable the full scope of the claims as a matter of law. *Wyeth*, 720 F.3d at 1386.

Second, the claims as construed include as part of their scope effective 2' methyl up nucleosides with fluoro in the 2' down position. Idenix witnesses testified that it was not until 2005—five years after the alleged priority date, and after reading Pharmasset's patent application—that highly-trained Idenix chemists were able to make and isolate 2' methyl up nucleosides with fluorine at the 2' down position. Idenix witnesses also testified that the specification does not disclose 2' methyl up, 2' fluorine down compounds—which include the Accused Products—even though it discloses the use of fluorine at other substituent positions. Federal Circuit authority holds that this does not satisfy enablement as a matter of law. *See Liebel-Flarsheim*, 481 F.3d at 1380.

A. The '597 Patent's Plan for Screening Compounds Using Assays Does Not Enable the Full Scope of the Claims under the *Wands* Factors

The testimony of Idenix's witnesses at trial relating to the *Wands* factors established that the '597 patent presents a research plan for identifying effective compounds by screening what Idenix's expert Dr. Meier described as "a lot of compounds," using biological assays. Tr. 1918:11 (Meier). The Federal Circuit in *Wyeth* deemed this "undue experimentation" as a matter of law.

In *Wyeth*, the claims recited a method of treating restenosis by administering an "effective amount of rapamycin." 720 F.3d at 1382. Rapamycin is a "class of compounds." *Id.* The specification disclosed "*in vivo*" and "*in vitro*" testing data showing that one member of this class, sirolimus, was effective and thus practiced the claims. *Id.* at 1383. It was known that sirolimus acts by binding two proteins in its "macrocyclic ring." *Id.* The Federal Circuit accepted that a POSA would have known that four compounds with "the same macrocyclic ring as sirolimus" were also effective. *Id.* at 1385. Defendant Abbott argued that, in addition to these five compounds, "there could be millions of compounds made by varying the substituent groups outside of sirolimus's macrocyclic ring." *Id.* at 1384. The Court accepted Wyeth's assertion that a POSA would have reduced the number of candidate compounds by excluding those without a similar molecular weight to sirolimus, decreasing the class of candidates screened to "tens of thousands of candidates." *Id.* at 1384-85. And as to determining which of these tens of thousands of compounds were effective, the Federal Circuit "accept[ed] as true that one of ordinary skill could **routinely** use the assays disclosed in the specification to determine … the effects in candidate compounds." *Id.* at 1385.

At summary judgment, Wyeth argued that the claims were enabled because "a skilled artisan could ascertain whether a candidate rapamycin compound has the same macrocyclic ring as sirolimus" and "could routinely determine whether a candidate [was effective] using the assays disclosed in the specification." *Id.* at 1384. The Federal Circuit disagreed and held as a matter of law that the disclosed research plan did not enable the full scope of the claims. Directly applicable here, the Court stated: "The remaining question is whether having to synthesize and screen each of at least tens of thousands of candidate compounds constitutes undue experimentation. We hold that it does." *Id.* at 1385. Subsequent Federal Circuit cases have held that large-scale research plans aimed at identifying the claimed embodiments are not sufficient to enable the full scope of the claims. *See Promega Corp. v. Life Techs. Corp.*, 773 F.3d 1338, 1349 (Fed. Cir. 2014) (citing *Wyeth*, 720 F.3d at 1385). The facts of this case—as described below by Idenix's witnesses—are directly analogous.

1. As in *Wyeth*, the '597 Patent Provides Experimental Data on Only a Few Compounds

The '597 patent reports biological assay data on four compounds, which are depicted in Figure 1. PX-1525, Fig. 1, Examples 4-7; Tr. 1856:24-1864:19 (Meier). Each has a 2'-methyl up and a hydroxyl ("OH") at 2' and 3' down. The only difference among them is the base (A, U, C or G). PX-1525, Fig. 1; Tr. at 386:5-13, 387:18-388:4 (Sommadossi). Only one compound is expressly described as "active." PX-1525 at 140:49. But for this motion, Gilead assumes Dr. De Francesco testified that a POSA would believe all four compounds are active. Tr. 2003:25-2006:25.

2. As in *Wyeth*, Idenix Testified that the Specification Discloses a Screening Plan for Identifying Compounds Effective to Treat HCV

As construed, the claims are not limited to the four 2' methyl up, 2' OH down compounds tested in the assays. Idenix's Drs. Meier and De Francesco testified that, as in *Wyeth*, the specification directs a POSA to a group of compounds to be screened for effectiveness. This testimony is just like the *Wyeth* testimony that resulted in invalidity as a matter of law.

The number of compounds to be screened is "a lot": As construed, the structural limitations in the claims encompass nucleosides with a methyl group in the 2' up position, *any* substituent other than hydrogen at the 2' and 3' down positions, any substituent at other substituent positions on the nucleoside, and any purine or pyrimidine base. Idenix's Dr. Meier confirmed this by pointing to Formula XI as one example of compounds within the scope of the claims. He testified that, when R^6 (corresponding to 2' up) is held to methyl, the formula is an embodiment of the claim. Tr. 1865:6-1866:6. Formula XI lists potential modifications for the following positions other than 2' up: Base, R^7, OR^2, and OR^1. *See* PX-1525 at 10:30-55. The formula gives a large number of substituent candidates at each position. These substituents include alkyl, lower alkyl, purine or pyrimidine base, and acyl—each of which itself represents a large set of additional possible substituents. *Id.* at 10:30-41, 37:19-38:29. The same also holds true for Formulas X and XVII, each of which accommodates a 2' methyl up, and all of which describe the use of a large, closed set of

substituent options at other available substituent positions on the molecule. *Id.* at 10:1-54; 12:19-67.

In response to Dr. Secrist's testimony that the structural limitations, after limiting the 2' up position to methyl, includes billions of potential nucleosides,[1] Dr. Meier did not proffer an alternative figure. He observed that "if you take the theoretical approach to discuss all the structures that are mentioned in the '597 patent . . . then there are **very – a lot of compounds**." Tr. 1918:8-11 (Meier). But he disagreed that all these "a lot of compounds" would be effective to treat HCV, as required by the claim. Whether described as more than one billion or "a lot of compounds," Dr. Meier testified a POSA would arrive at a "significantly smaller" number by focusing on compounds with 2' methyl up that are active as *"***inhibitor[s] of NS5B [the HCV] polymerase**.*"* Tr. 1918:7-19. But, as confirmed by Drs. Meier and De Francesco, the patent identifies screening as the tool to determine whether a compound is an inhibitor of the NS5B polymerase. "[Y]ou don't know whether a nucleotide will have activity against HCV until you make it and test it." Tr. 1333:12-16 (Gosselin).

The testimony of Drs. Meier and Secrist is in substantive agreement. Dr. Secrist testified that the structural limitations cover more than one billion compounds **before** screening for those active against HCV, but only a "small number of compounds . . . would be effective" within this group. Tr. 1578:7-18. Dr. Meier had an opportunity to provide a different number, but he instead characterized those variants as "very - a lot of compounds." Tr. 1918:8-11. He then pivoted and spoke about the "significantly smaller" set of 2' methyl up compounds that are "inhibitor[s] of NS5B polymerase." Tr. 1918:7-19. As confirmed by Drs. Meier and De Francesco, the patent identifies screening as the tool to determine if a compound inhibits NS5B polymerase. The Court can credit Dr. Meier's testimony in full. Under *Wyeth*, 720 F.3d at 1385-86, the need to screen "a lot of compounds" to identify the "significantly smaller" number of effective ones lacks enablement as a matter of law.

[1] *See* Tr. 1577:4-25 (Secrist). In performing his analysis that there were more than one billion possible variants based on assuming 2' methyl up, Dr. Secrist approached it from the standpoint that POSAs "are going to bring their knowledge and they're going to look at what's in the patent" and therefore would not select substituents such as C_{100}. Tr. 1724:2-9 (Secrist).

The Patent instructs a POSA to discover active compounds using screening: Drs. Meier and De Francesco testified that screening is needed to find the compounds that are active against the NS5B/HCV polymerase. Dr. Meier pointed to a statement in the specification that "[n]ucleosides can be screened for their ability to inhibit HCV polymerase activity in vitro according to screening methods set forth more particularly herein," as well as listed references describing "how to run such a polymerase assay." Tr. 1854:12-1856:10. He summarized that, "within the patent, there are screening methods described or included to test the compounds for the activity [against HCV polymerase]." *Id.* Dr. De Francesco also testified that "nucleosides can be screened for ability to inhibit HCV polymerase activity in vitro. . . . We use the screening because that is the way you actually cut down the number of compounds, by removing all the inactive ones to a few interesting ones." Tr. 1969:22-1970:25, 1980:8-1984:10; *see* Tr. 1488:6-16 (Seeger). The specification repeatedly instructs screening to identify active compounds. PX-1525 at 13:43-49, 36:43-49, 139:29-59.

Simply put, Drs. Meier and De Francesco testified that the '597 patent discloses the use of certain assays to "cut down the number of compounds, by removing all inactive ones," (Tr. 1970:7-25) (De Francesco), to obtain the "significantly smaller" list of 2' methyl up compounds that may be effective from the starting point of "a lot of compounds." Tr. 1917:20-1918:19 (Meier). This is exactly what the Federal Circuit found insufficient in *Wyeth*, where the patentee argued that the compounds to be tested numbered in the "tens of thousands" and that this number could be decreased through a process of synthesis and screening. *Wyeth*, 720 F.3d at 1385.

Drs. Meier and Francesco's testimony that screening is required to identify effective compounds is unsurprising. Dr. Meier testified "the field was in its infancy in 2000-2001," the field being "modified nucleosides activity for HCV." Tr. 1927:23-1928:5 (Meier). He testified that a POSA would understand that the "key of these compounds is the methyl group in the 2' position, up." Tr. 1867:9-12 (Meier). His focus on 2' methyl up was a central theme of his testimony. Tr. 1917:14-19; 1919:1-4 (Meier). This is precisely the approach the Federal Circuit found wanting in

Wyeth, where it was known that the macrocyclic ring structure on sirolimus was essential, and that four other compounds with this structure were effective, but that substantial testing was required to identify other active compounds falling with the claims. *Wyeth*, 720 F.3d at 1386.

Dr. De Francesco testified that *in vitro* screening for activity against HCV polymerase could be done at an average of "6,000 compounds per month." Tr. 1989:2-13.[2] For context, at this rate it would take 13,888 years to screen one billion compounds—the only number in the record as to the scope of the structural limitations—for HCV polymerase activity. But even if the number of compounds covered by the structural limitations were smaller by a factor of 1000 (i.e., one million), it would still take over 166 months (13.8 years) to screen them for HCV polymerase activity. Moreover, *in vitro* screening is only part of the process. Before a compound can be screened, it must first be made. In the 2001-2002 time period, Idenix was in the business of making and screening nucleosides. Idenix testified that, during this time period, for Idenix to be able to test 37 compounds a month for activity "seems like a lot." Tr. 1201:18-1203:6 (Tausek). At that rate, per Idenix's own metrics, synthesizing and screening one million compounds would take over 2252 years.

3. Because the '597 Patent Claims are Not Limited to HCV Polymerase Activity, Idenix's Experts Provided Legally Improper Testimony

Gilead submits that the above analysis establishes non-enablement as a matter of law. But there is a second defect in Idenix's testimony. Its witnesses focused solely on finding compounds that act against the HCV polymerase. The patent says "[c]ompounds can exhibit anti-hepatitis C activity by inhibiting HCV polymerase, by inhibiting other enzymes needed in the replication cycle, or by other pathways," and it provides assays that detect activity other than against the polymerase, including kinase and protease activity. PX-1525 at 139:30-32; 139:52-59. Consistent with this disclosure, the claims as construed are not limited to activity against the HCV/NS5B polymerase. At

[2] Dr. Meier testified the patent requires further time consuming tests beyond HCV polymerase screening to show effectiveness. PX-1525 at 139:60-140:35 & Tr. 1857:7-17; PX-1525 at 140:38-67 & Tr. 1860:22-1861:12; PX-1525 at 141:30-142:55 & 1862:17-1864:19.

Idenix's request, the Court construed the claims to require a compound that "is effective to treat HCV," without limiting the mechanism of action to the HCV polymerase. D.I. 431 at 10, 11-12. Idenix's on-the-fly attempt to re-construe the claims to the HCV polymerase was legally improper.[3]

The significant enablement problem that Idenix created was not an accident. Idenix needed the structural limitations in its claims to be construed broadly to sweep in Gilead's Accused Products. And it sought an efficacy limitation to exclude inoperative embodiments. Idenix's solution at trial was to fall back on a description of a large-scale screening plan that a POSA would employ to discover active compounds within the construed scope of the claims. As *Wyeth* holds, a patent disclosure that provides merely "a starting point" and an invitation "to engage in an iterative, trial-and-error process to practice the claimed invention," lacks enablement. *Wyeth*, 720 F.3d at 1386.

B. Idenix's Testimony Establishes that the '597 Patent Does Not Enable the Synthesis of the Full Scope of Compounds Encompassed by the Claims Under the *Wands* Factors

Idenix's infringement claim required a construction that includes as part of its full scope compounds with 2' methyl up, 2' fluoro down, as in the Accused Products. The Court construed the claims as Idenix proposed. The Court must now decide if such claims are enabled as a matter of law.

Idenix witnesses testified that, from 2002 to 2005, Idenix repeatedly tried **and failed** to make and test an unprotected 2' methyl up, 2' fluoro down nucleoside. Tr. 1172:5-1183:17 (Griffon); DX-268; DX-2184; Tr. 1188:5-1194:6 (Stewart); DX-359. Even consulting world-renowned experts on fluorine chemistry did not help Idenix. Tr. 1158:8-1159:24 (Storer), 1168:17-1170:1 (Griffon). Idenix sought a 2' methyl up, 2' fluoro down nucleoside because its CEO "heard" from Pharmasset's founder that it "was good." Tr. 1160:20-1161:22 (Storer); DX-305; Tr. 1196:16-1198:10 (Wang). Idenix scientists testified that they only successfully made and tested such a

[3] At trial, Gilead elicited testimony that nucleosides do not just act by attacking the HCV polymerase. Tr. 1263:19-1264:6; 1240:11-1241:23; 1591:23-1592:14; DX-922. Idenix's solution was to present testimony from Dr. Meier that simply re-construed the claims.

nucleoside after following the synthesis in Pharmasset's (now Gilead's) 2005 patent application. Tr. 1183:9-17, 1186:12-17 (Griffon); Tr. 1193:5-11 (Stewart); Tr. 1196:10-1199:3 (Wang).[4]

Idenix's clear testimony that it was not able to make and test 2' methyl up, 2' fluoro down compounds renders the claims invalid. The Federal Circuit's ruling in *Liebel-Flarsheim*, 481 F.3d at 1380, is on point. The patent claimed a method of loading a syringe into a fluid injector having a "syringe receiving opening." The claims originally filed were limited to syringe openings *with a jacket*, but the patentee removed the jacket limitation during prosecution after learning of the defendant's product design. *Id.* at 1373-74. The Court found the claims invalid as a matter of law, as their "full scope must be enabled," yet the specification did not enable a jacketless design. *Id.* at 1378-1379. The Court identified two key points to its decision: (1) "nowhere does the specification describe an injector with a disposable syringe without a pressure jacket," indeed it discussed the jacket as important; and (2) "[t]he inventors admitted that they tried unsuccessfully to produce a pressure-jacketless system and that producing such a system would have required more experimentation and testing." *Id.* at 1379. In the words of the Federal Circuit, "Liebel successfully pressed to have its claims include a jacketless system, but, having won that battle, it then had to show that such a claim was fully enabled . . . . The motto, 'beware of what one asks for,' might be applicable here." *Id.* at 1380; *see also Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1285 (Fed. Cir. 2007).

As in *Liebel-Flarsheim*, Idenix's witnesses testified that the patent does not disclose fluoro in the list of substituent candidates at the 2' down position. Tr. 456:17-457:3 (Sommadossi); Tr. 1931:9-16 (Meier). Rather, they agreed that the specification discloses fluoro in other positions, such as the 2' up position. Tr. 1931:9-19 (Meier). Moreover, just as in *Liebel-Flarsheim,* 481 F.3d at 1379, Idenix repeatedly "tried unsuccessfully to produce" and test 2' methyl up, 2' fluoro nucleosides.

[4] "[A]bsence of a commercial embodiment" may be "relevant to enablement." *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1260-61 (Fed. Cir. 2004). But to be clear, the '597 patent's lack of enablement is in its specification. The Court need not reach or consider Idenix's product difficulties.

The same is true of Idenix's original claims filed in 2001: they too contained only a closed set of substituents at 2' and 3' down that did not include fluorine at 2' down. PX-1813A at 195-267. After Pharmasset successfully created 2' methyl up, 2' fluoro down compounds, Idenix broadened its claims.[5] This Court held that the new claims encompass Gilead's 2' methyl up, 2' fluoro down compounds. D.I. 237 at 12; D.I. 238 at 2. But having elected this claim construction strategy, Idenix was required to have enabled the full scope of its broad claims—and failed to do so.

Idenix has suggested it need not enable the 2' methyl up, 2' fluoro down scope of the claims because it was "later-conceived technology." D.I. 317 at 15. This argument lacks merit. Fluorine as a nucleoside substituent is referenced in the '597 patent itself at other positions on the nucleoside. *E.g.*, PX-1525 at Fig. 1 ("FIAU"). The key failing of the patent is that it provides no "specific and useful" guidance on the use of 2' methyl up with fluorine *at the 2' down position*, as evidenced by Idenix's testimony that they could not make and test such compounds. This is the essence of non-enablement.[6] *See Plant Genetic Sys. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1340 (Fed. Cir. 2003). Idenix chose to claim the open-ended group of effective compounds with *any* non-hydrogen substituent at 2' and 3' down. The specification must enable this open-ended scope. *See MagSil Corp. v. Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1379, 1384 (Fed. Cir. 2012) (invalidating open-ended claim because the specification did not enable the future advances that the broad claim sought to capture).

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[5] Although the Court need not reach the issue to grant this motion, there is no enablement in the specification for anything beyond 2' methyl up, 2' OH down compounds. Dr. Meier testified that the specification only contains synthesis for 2' methyl up, 2' OH down molecules and Dr. Secrist agreed. Tr. 1922:2-1925:3 (Meier); Tr. 1595:23-1596:9 (Secrist).

[6] This is contrasted with a case such as *In re Hogan,* in which the claim recited a "solid homopolymer of 4-methly-1-pentene." 559 F.2d 595, 597 (C.C.P.A. 1977). The patent application claimed priority to a 1953 parent application. The specification disclosed what was as of 1953 "the only then existing way to make such a polymer." *Id.* at 606. It was not until 1962 that a new method for making the claimed polymer appeared. The presence of at least one method of making the full scope of the claim as of the priority date was sufficient. In the case at bar, the defect was the inability to enable *any* method of making 2' methyl up, 2' fluoro down. Moreover, if 2' fluorine substituents for nucleosides are after-arising technology, it would defeat written description. *Chiron*, 363 F.3d at 1254.

II. THE CLAIMS AS CONSTRUED LACK WRITTEN DESCRIPTION

At Idenix's urging, the Court construed the claims as requiring "a beta-D-pyrmidine nucleoside that includes a five member sugar ring with a methyl group in the 2' up position **and non-hydrogen substituents at the 2' down and 3' down positions**," and which is effective to treat HCV. D.I. 237 at 12; D.I. 238 at 2. As construed, this requires the presence of 2' methyl up and substituents at 2' and 3' down, but permits 2' and 3' down to be *anything* other than hydrogen.

In reaching this construction, the Court referenced statements Idenix made during prosecution of the '597 patent's parent application. D.I. 237 at 8, 12. But while prosecution statements years after the priority date can be relevant to claim construction, they cannot supply a written description to support a claim. A written description must be in the specification itself.[7] All portions of the specification identified by both parties' experts as relevant provide only a closed, defined list of substituents at 2' down, and never an open-ended list of any substituent but H.[8] This renders the claims invalid.

Written description requires that the specification show "possession of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351. "[T]he test requires an objective inquiry into the four corners of the specification from the perspective of a [POSA]." *Id.* JMOL of invalidity for lack of written description is required if this objective, four corners standard is not met. *See, e.g.*, *Novozymes A/S v. Dupont Nutrition Biosciences APS*, 723 F.3d 1336, 1351 (Fed. Cir. 2013).

A patent "can also be held invalid for failure to meet the written description requirement

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[7] Idenix told the PTO that "[t]he unifying concept in the remaining claims is that each is a pyrimidine nucleoside that has two non-hydrogen substituents in the 2' position of the nucleoside which represents the core of the invention" (10/31/03 Am. at 13; 8/26/03 Am. at 11; 6/6/03 2nd Am. at 11). These statements are not in the patent and came over two years after filing. In August and June 2003, all "remaining claims" pending recited substituents at 2' and 3' down that were either OH or in a defined, closed list. In October 2003, Idenix added claims to a "β-D-2'-C-branched pyrimidine nucleoside" (different from the issued claims). But the specification again describes this with closed lists of substituents (R7 and R9) at the 2' and 3' down positions. PX-1525 at 47:1-35.

[8] This error can also be described using the following formulation: the subgenus of 2' methyl up with *any* non-hydrogen substituent at 2' and 3' down is not described.

based solely on the face of the patent specification," regardless of witness testimony. *Centocor Ortho. Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1347 (Fed. Cir. 2011); *see also PIN/NIP, Inc. v. Platte Chem. Co.,* 304 F.3d 1235 (Fed. Cir. 2002); *Univ. of Rochester v. G.D. Searle & Co.,* 358 F.3d 916, 927 (Fed. Cir. 2004). Moreover, expert testimony cannot supply a description that is missing from the specification, and generalizations by an expert as to what the specification discloses are legally insufficient to sustain a verdict. *See PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d. 1299, 1306 (2008); *Anascape, Ltd. v. Nintendo of Am., Inc.*, 601 F.3d 1333, 1341 (Fed. Cir. 2010). The law of written description requires that the specification itself "actually or inherently discloses the claim element." *PowerOasis,* 522 F.3d at 1306; *see also Ariad,* 598 F.3d at 1352 ("[A] description that merely renders the invention obvious does not satisfy the requirement.").

Thus, the relevant question is where, in the four corners of the specification, does it disclose that effective 2' methyl up compounds can have *any* non-hydrogen substituents at 2' and 3' down?

A. Because of Idenix's Failure to Apply a Four-Corners Objective Standard, There Is No Written Description as a Matter of Law

Gilead's expert Dr. Secrist testified that, for 2' methyl up molecules, the specification defines possible 2' down substitutions by disclosing only a "narrower," list of specific substituents. Tr. 1606:13-1609:8, 1612:19-1613:7.[9] In patent parlance, the specification defines a closed list of substituents at the 2' down position, such that the subgenus of 2' methyl up and anything but hydrogen at the 2' and 3' down is not disclosed, as opposed to an open list that would allow for anything at those positions.

As required by the Federal Circuit, Dr. Secrist's testimony was objectively consistent with the four-corners of the specification. The '597 patent specification always provides a closed, defined list

[9] Dr. Secrist also testified that the patent never discloses effective 2' methyl up nucleosides with any purine or pyrimidine at 1' up, and any substituent at 3' up, 4' and 5'. Tr. 1577:4-16; 1587:18-1589:23; 1571:10-22; 1578:7-1579:2; 1581:8-25; 1583:6-25; 1593:17-1594:1; 1606:13-21; 1613:4-25; 1746:5-22. This is an independent basis for invalidity due to no written description.

of substituents every time it discloses a substitution at 2' (and 3') down. The "Summary of the Invention" section states: "Compounds, methods and compositions for the treatment of hepatitis C infection are described that include an effective hepatitis C treatment amount of β-D or β-L nucleoside of the Formulas (I)–(XVIII), or a pharmaceutically acceptable salt or prodrug thereof." PX-1525 at 5:24-28. The formulas define a closed set of specific substituents at the 2' (and 3') down positions; the closed list is given by the definitions of R^2/R^3 and R^7/R^9. *See, e.g.*, PX-1525 at 5:46-58, 6:20-32, 6:63-7:9, 7:43-56, 8:20-33, 8:58-9:2, 9:46-59, 10:30-53, 11:19-30, 12:5-12, 12:55-62, 13:34-38; Tr. 1596:14-1597:8, 1606:13-1609:8 (Secrist). There is no open-ended qualifier in these definitions, such as "including but not limited to." Rather, each states that "a compound of Formula [I-XVIII] . . . is provided," a structure is depicted, and when that structure discloses a substituent at the 2' or 3' down positions, a closed definition is provided.

The Figures and "Detailed Description" also provide closed lists of substituents. The Figures are limited to OH at 2' (and 3') down. Tr. 1754:10-22 (Secrist). The patent's "Detailed Description" section states: "**The invention** as disclosed herein **is a compound, method and composition** for the treatment of hepatitis C . . . that includes administering an effective HCV treatment amount of a β-D- or β-L-nucleoside **as described herein** or a pharmaceutically acceptable salt or prodrug thereof." PX-1525 at 15:40-16:10. In all remaining sections, each "β-D- or β-L-nucleoside" with modification at 2' or 3' down specifies a closed definition of substituents, either R^2/R^3, R^7/R^9, or a smaller subset. *See id.* at 16:33-44, 17:16-28, 17:65-18:9, 18:49-61, 19:36-48, 20:20-32, 21:12-24, 22:23-36, 22:44-49, 23:25-36, 23:65-24:9, 25:5-10. The same is true of the original claims filed in 2001: they recited only a closed set of substituents at 2' (and 3') down. PX-1813A at 195-267.

Despite the closed definitions in the specification, Idenix did not seek a construction limited to the closed lists of 2' substituents. That would have defeated its infringement claim, as the closed lists exclude fluorine at 2' down, which is in the Accused Products. But that choice carries consequences for written description. The Federal Circuit's decision in *ICU Med., Inc. v. Alaris Med.*

Sys., 558 F.3d 1368 (Fed. Cir. 2009), is on point. The specification described a valve with several features, one of which was a spike. The patentee later obtained claims without the spike limitation, such that the claims read on both valves with *and without* spikes. *Id.* at 1377-78. The Federal Circuit held that, because the patentee "failed to point to any disclosure in the patent specification that describes a spikeless valve," claims that encompass spikeless valves were invalid. *Id.* at 1379. The Court rejected arguments that a POSA could envision changes to the disclosed structures, as "[i]t is not enough that it would have been obvious" that the valve "could be used without a spike." *Id.*

The same shortcoming is true of Dr. Meier's trial testimony. In response to Dr. Secrist's analysis that every relevant passage in the '597 patent's specification limits 2' down substituents to a defined list, Dr. Meier declined to engage the issue. First, he pointed to Figure 1, Examples 5-7, and Formula XI as locations of support for "2'-methyl ribonculeosides." Tr. 1866:12-21 (Meier). But in all instances he testified that those passages disclose either OH in the 2' down position, or a closed list of substituents. Tr. 1856:24-1860:6, 1867:9-12, 1863:11-15, 1865:2-1866:6 (Meier).

Dr. Meier then testified that "the patent [is not] limited to having a hydroxide at the 2' down position." Tr. 1860:3-6. He also relied on a Pharmasset grant application to suggest that others had concluded "the key invention in this patent application is the methyl up modification." Tr. 1908:7-10 (Meier); *see* PX-764. And he relied on a third-party publication that he believed describes work in the patent specification as a "novel series of compounds." Tr. 1910:21-9111:6 (Meier); *see* PX-702.

This testimony is legally insufficient because it addresses the wrong questions. The issue is not whether the specification *limits* itself to OH. Nor is it whether the articles and grant application recognize *methyl up* as the "key" invention. The claims as construed recite not only methyl up, but also a substituent at 2' and 3' down that can be *anything* other than hydrogen. As such, the relevant question for written description is: where, in the four corners of the specification, does it disclose that effective 2' methyl up compounds can have *any* non-hydrogen substituents at 2' and 3' down?

The Federal Circuit holds that generalized statements such as those by Dr. Meier are

insufficient as a matter of law. In *Anascape,* the specification repeatedly described a controller with a set of features, one of which was a "single input member operable in six degrees." *Anascape*, 601 F.3d at 1335. In a continuation application, the patentee obtained a claim that was not limited to a single input member operable in six degrees. *Id.* at 1340-41. Instead of pointing to objective language in the specification disclosing a controller without the single input member but with all the other features, the patentee's expert fell back on generalized testimony: "Dr. Howe testified that 'the ['525] patent is simply not limited to a single input 6-degree-of-freedom controllers' and the claims which do not concern those are—find support in both the 1996 application and the '700 patent.'" *Id.* at 1339. The Federal Circuit held that it was legal error to credit such generalized expert testimony, which "cannot override the objective content of these documents [the specifications]." *Id.*

In *PowerOasis*, 522 F.3d at 1310, an expert testified that the inventors were in possession of a user interface on a laptop computer. But the expert "point[ed] to figures and discussions of the user interface in the Original Application, each of which is to a user interface on [a] *vending machine*." *Id.* He also offered generalizations as to what "those of ordinary skill" would understand. *Id.* The Court held that, "[a]t best, this is a statement that it would be obvious" to make a laptop user interface. *Id.* As the expert did not point to where "the written description actually or inherently disclose[s] the claim element," JMOL of invalidity for lack of written description was proper. *Id.* at 1306, 1310.

Idenix has relied on *Utter v. Hiraga,* 845 F.2d 993, 998 (Fed. Cir. 1988), to argue that a specification may "contain a written description of a broadly claimed invention without describing all species that claim encompasses." The issue here is different: There is no disclosure of a "broadly claimed invention" that a 2' methyl up compound can be effective with *any* non-hydrogen substituents at 2' and 3' down. Rather, the only relevant disclosures in the specification are a defined, closed lists of substituents. *See* PX-1525 (citations *supra*). A written description "must do more than merely disclose that which would render the claimed invention obvious." *ICU*, 558 F.3d at 1377.

B. Gilead Renews the Other Elements of Its Motion on Failure to Show Possession of the Claim Scope

Gilead moved for summary judgment of no written description, among other reasons, because the specification does not show possession beyond certain 2' methyl up, 2'/3' OH down molecules. D.I. 288; D.I. 378. In denying these motions, the Court pointed to Idenix's proffer that Dr. Meier would testify that the specification shows "possession of a definite class of compounds . . . that resemble the naturally occurring substrate of the HCV polymerase sufficiently to be useful to inhibit HCV polymerase." D.I. 446 at 16. Aside from whether this is legally sufficient (it is not), **Dr. Meier gave no such testimony at trial**. Thus, Gilead renews its request on the other points in its summary judgment motions.

III. IDENIX PRESENTED A LEGALLY IMPROPER DAMAGES CASE AT TRIAL

A. Mr. Carter Did Not Present the Required Comparability Analysis

Idenix asked for a 10% royalty on the entirety of Gilead's net sales. For support, Mr. Carter relied solely on two agreements as allegedly comparable—Pharmasset-Roche (PX-1132) and Merck-Roche (PX-1606).[10] But Mr. Carter violated Federal Circuit law by not establishing comparability.

The Federal Circuit has "stressed that comparisons of past patent licenses to the infringement must account for 'the technological and economic differences' between them." *Wordtech Sys., Inc. v. Integrated Network Sols., Inc.*, 609 F.3d 1308, 1320 (Fed. Cir. 2010). The remedy for failure to present a proper comparability analysis to the jury is JMOL. *See Whitserve, LLC v. Comput. Packages, Inc.*, 694 F.3d 10, 32 (Fed. Cir. 2012) ("'[S]uperficial testimony' and the simple recitation of royalty numbers . . . will not support the jury's award when no analysis is offered . . . .").

Mr. Carter's testimony failed to lay that required foundation. His "comparability" analysis for the two agreements together spanned fewer than 20 lines of testimony, which is copied in full below:

[10] Mr. Carter also introduced rates from a Gilead survey of acquisitions of compounds, which he improperly described as "comparable transactions that occurred in the marketplace." Tr. 738:8-18. It was improper for these rates to be published to the jury, further supporting JMOL or a new trial.

> I considered it **[Pharmasset-Roche agreement]** to be comparable because first of all it was for the 6130 drug and the related patents around it. That is the Jeremy Clark drug we kept hearing about. The second reason was because we are talking about Pharmasset licensing Roche, so Pharmasset, again, a smaller development company, similar to Idenix, is licensing Roche, a large drug company, that would be doing all the work and selling the product, similar to what Gilead would be doing.
> . . . .
> So this **[Merck-Roche] agreement**, it is for a patent, this agreement is for a patent related to Hepatitis C medication that Merck has. And Merck is licensing Roche. And Roche needs to take that patent and then, in effect, do all the rest of the work, so it's similar to, again, this hypothetical negotiation with Idenix and Gilead where Gilead has a—Idenix has a patent and Gilead will be doing the work.

Tr. 742:4-12 (Carter) (re Pharmasset-Roche agreement), 744:7-13 (re Merck-Roche agreement).

Following this very limited testimony on "comparability," in reaching his conclusions, Mr. Carter relied directly on the rates in the two agreements without any adjustment. He testified that the agreement rates were "from ten percent to 18 percent" and used this as the support for his 10% royalty opinion. Tr. 742:13-743:14, 747:2-12. In closing, Idenix relied on the same range. Tr. 2151:22-2152:2 ("up to 18 percent."). This was legally improper under Federal Circuit law, as Mr. Carter's testimony failed to lay a foundation that he accounted for the technological and economic differences between each agreement and the hypothetical license.

First, Mr. Carter did not lay a foundation that he accounted for the two agreements each licensing a *portfolio* of patents, not just a *single* patent. The Pharmasset-Roche agreement licensed every patent Pharmasset owned during the term that was necessary to commercialize the 6130 compound. PX-1132 at 6 (§ 1.56); *id.* at 9 (§ 2.1(a)). The Merck-Roche agreement similarly provided a covenant not to sue for every patent Merck controlled while Roche would be paying royalties relating to the compound. PX-1606 at 4 (§ 2.4); Tr. 779:7-780:6 (Carter); *see also TransCore, LP v. Elec. Transaction Consultants Corp.*, 563 F.3d 1271, 1275-76 (Fed. Cir. 2009) (covenant not to sue is same as a license). This was improper as a matter of law. *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1328 (Fed. Cir. 2009) ("[A] reasonable juror could only conclude" that a license to an "entire patent portfolio" was "vastly different" from a license to "only one patent."); *Trell v. Marlee Elecs. Corp.*, 912

F.2d 1443, 1446-47 (Fed. Cir. 1990) (damages in a single patent case may not be based on a prior license that "encompassed the right to other inventions" and not just a single patent); *see also AVM Techs., LLC v. Intel Corp.*, No. 10-cv-610-RGA, 2013 WL 126233, at *3 (D. Del. Jan. 4, 2013) (patentee "may not argue" that "licenses granting rights to entire portfolios of patents are comparable to a license that the parties would have negotiated for a single asserted patent").

Second, Mr. Carter did not even identify, much less analyze, any of the patents licensed in either agreement. For the Merck-Roche agreement, Mr. Carter's testimony was so deficient that the copy of the agreement introduced at trial did not even include the list of licensed patents. PX-1606.[11] Having failed to discuss or even identify the licensed patents, Mr. Carter plainly did not meet his obligation to account for "the technological . . . differences between those license[d] [patents] and the ['597] patent." *ResQNet.Com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 873 (Fed. Cir. 2010).

Third, Mr. Carter failed to lay a foundation as to the impact of the transfer of many non-patent assets. Tr. 774:3-5, 773:6-13 (Carter). Mr. Carter testified that the Pharmasset-Roche "collaboration agreement" gave Roche not just a patent portfolio license. It was for the "6130 drug," and included rights to assets and know-how "separate from any patent rights." Tr. 742:4-5, 775:6-777:23 (Carter). This again violated Federal Circuit law. *See ResQNet.com*, 594 F.3d at 870 ("re-bundling" agreements not comparable because they transferred multiple non-patent assets).

Finally, Mr. Carter failed to lay a foundation to account for the *timing* of the two Roche agreements (negotiated years before expected FDA approval) compared to the hypothetical license (negotiated after FDA approval). Mr. Carter testified that at the time of the Roche agreements there was risk of failure for the licensed compound. Tr. at 785:4-786:16. Mr. Carter testified that he did

[11] Even for the one patent in the Merck portfolio that Mr. Carter vaguely referred to *without* identifying it, he testified only that the patent allegedly covers a "Hepatitis C medication that Merck has." Tr. 744:7-13. This was insufficient. A technical comparability analysis cannot focus just on the covered *product*; rather, it must "describe the relationship between the *patented technology licensed therein* and the licensee's products." *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1316 (Fed. Cir. 2011).

not take into account the impact of differences in risk. He testified that it was "neither here nor there" because Roche had "**high hopes**" of obtaining FDA approval. Tr. at 7845:4-8. Mr. Carter further testified that, at the hypothetical negotiation, Gilead had removed the risk of failure for sofosbuvir. Tr. at 786:17-787:21. In *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 871 (Fed. Cir. 2003), the Federal Circuit held that agreements with different risk levels were not comparable. For the same reason, Mr. Carter's failure to take into account differential risks was also improper.

B. Mr. Carter and Idenix Repeatedly Violated the Entire Market Value Rule

At trial, Idenix and its expert Mr. Carter sought a 10% royalty applied to a base consisting of all $25.4 billion of Gilead's adjusted net sales of sofosbuvir. Tr. at 749:16-752:18. Under the Entire Market Value Rule ("EMVR"), the total value of an accused product can be used as a royalty base *only if* the patentee establishes that "the patented feature creates the basis for customer demand." *Virnetx, Inc. v. Cisco Sys., Inc.*, 694 F.3d 1308, 1326 (Fed. Cir. 2014). The Federal Circuit created this rule to prevent a plaintiff who has not met that burden from relying on large revenues in its damages case, which "cannot help but skew the damages horizon" and "artificially inflate the jury's damages calculation beyond that which is 'adequate to compensate for the infringement.'" *LaserDynamics, Inc. v. Quanta Comput., Inc.*, 694 F.3d 51, 68 (Fed. Cir. 2012). That is precisely what happened in this case.

Idenix and Mr. Carter made it a central theme of their damages case to repeatedly invoke Gilead's large revenue numbers. As but one example, Idenix and Mr. Carter repeatedly emphasized a "**pie chart**" with Idenix's 10% share "$2.54 billion in **the little green slice**" and a big slice showing that "$22.86 billion would stay with Gilead." Tr. 751:10-752:18 (Carter); *see* Tr. 730:11-18 (Carter) ("the little green 10% **sliver**"); Ex. A at 12-15, 21; Tr. 2152:8-25 (Idenix Closing). This was a textbook example of the type of trial conduct the Federal Circuit has held requires JMOL when EMVR is not satisfied. *See Uniloc*, 632 F.3d at 1318-19 (finding it "tainted the jury's damages deliberations" when patentee's expert "accented his point by reference to a prepared **pie chart**, showing Microsoft's $19.28 billion in revenue with a 2.9% **sliver** representing his calculated royalty

rate."). Idenix even went so far as to highlight Gilead's revenues of "42 billion dollars **worldwide**," even though no foreign patents were at issue in this case. Tr. at 2132:5 (Idenix Closing).

This conduct requires a grant of JMOL, because the testimony of Idenix's own witnesses at trial made clear that the '597 patent does not by itself create "the basis for customer demand" for sofosbuvir. *Virnetx*, 767 F.3d at 1326. The "evidentiary burden" for this test rested solely on Idenix, *Lucent*, 580 F.3d at 1337, and that burden was heavy, *LaserDynamics*, 694 F.3d at 68:

> It is not enough to merely show that the [patented feature] is viewed as valuable, important, or even essential to the use of the [accused product]. Nor is it enough to show that [the product] without [the invention] would be commercially unviable.

In response to Gilead's *Daubert* motion on damages, Idenix represented to the Court that the '597 patent "cover[s] the active metabolite," and it promised to present evidence at trial establishing that this was the basis of customer demand for sofosbuvir. D.I. 330 at 15. This was a promise unkept at trial, on a legal foundational issue that Idenix was obligated to satisfy.

To be sure, Mr. Carter testified that "the metabolites cure you and the patent in this case covers the metabolite." Tr. 793:22-794:2 (Carter). But he then testified that elements of sofosbuvir supplied solely by Gilead are essential to providing that cure. Mr. Carter testified that Gilead's contribution to the Accused Products included two elements that impact commercial demand separate from the '597 patent: "**Gilead has to provide [1] the drug that cures you, and [2] the prodrug that gets the curative drug in the body**." Tr. 746:12-21 (Carter). Mr. Carter's demonstrative further described "Gilead's Contribution" as "a compound for treating HCV" and "a prodrug for delivering the compound," and he separated these from the Idenix patent. Ex. A at 8.

Prodrug Element: The drug sofosbuvir includes: (1) a monophosphate of PSI-6206 that is converted into an active metabolite, and (2) a prodrug that delivers it to liver cells. Tr. at 1121:10-23 (Sofia). Once absorbed into liver cells, the prodrug detaches, and the active metabolite attacks the virus. Tr. 1071:13-1074:14 (Sofia); DX-2749 at 20. Idenix's Dr. Meier testified that, if the active metabolite "is not up taken by . . . a human being, . . . then it would never exert anti-viral activity."

Tr. 1861:9-12. Idenix's witnesses thus confirmed the prodrug's critical role in providing a cure: "the active metabolite . . . is what cures," (Tr. 794:11-13) (Carter), it is the "**prodrug that gets the curative drug in the body**" (Tr. 746:12-21) (Carter), and without delivery of the active metabolite into cells, it "would never exert anti-viral activity" (Tr. 1861:9-12) (Meier).

2' Fluoro Down: Idenix and its witnesses agreed that the monophosphate of PSI-6206 that converts into the active metabolite includes another element not in the '597 patent: a 2' fluoro down. Tr. 238:8-23 (Idenix Opening); Tr. 456:17-457:3 (Sommadossi); Tr. 1931:9-16 (Meier); *see* Tr. 1598:9-1599:11 (Secrist). There was undisputed testimony that, in sofosbuvir, a 2' methyl up with a 2' fluoro down is important to enabling efficacy and minimizing toxicity, thus reducing the severe side effects that plagued prior HCV treatments. Tr. 1146:6-1149:20 (Sofia); Tr. 1215:19-24 (McHutchison).[12]

At trial, Mr. Carter testified that, "**No**," he had not "**considered the Entire Market Value Rule as part of [his] opinion.**" Tr. at 792:11-19. Instead, he said he applied a "comparable license" approach. *Id.* But an EMVR theory by another name is still the same. *LaserDynamics*, 694 F.3d at 68:

> Whether called "product value apportionment" or anything else, the fact remains that the royalty was expressly calculated as a percentage of the entire market value of [the product] rather than a patent-practicing [feature] alone. **This, by definition, is an application of the entire market value rule**.

Idenix suggests the Federal Circuit created a "comparable license" exception to EMVR in *Commonwealth Scientific & Indus. Research Org. (CSIRO) v. Cisco Sys., Inc.*, 809 F.3d 1295, 1303 (Fed. Cir. 2015). D.I. 330 at 14. Not so. *CSIRO* concerned a damages model with a **fixed dollar** royalty per unit, not a percentage rate applied to a base. *CSIRO*, 890 F.3d at 1302-03. The Federal Circuit found that EMVR was simply "inapplicable," as the model "**did not apportion from a royalty base at all**." *Id.* at 1302. Sales revenue for the accused product was not part of the equation. *Id. CSIRO* is about what evidence can be used in a damages case. But EMVR still forbids pointing to total sales

[12] The prodrug and 2' fluoro down features of sofosbuvir are separately patented by Gilead. *See* Tr. at 1124:18-1125:22 (Sofia) (testimony re DX-2721, U.S. Pat. No. 7,964,580).

unless the invention is "the basis for customer demand." *Virnetx*, 767 F.3d at 1326.

Idenix has further argued that, because the prodrug and what becomes the active metabolite are physically linked together in one "smallest saleable patent-practicing unit," Idenix need not satisfy EMVR requirements. D.I. 330 at 12. Not so. In *Virnetx*, the Federal Circuit held that it "misstates our law" to "suggest[] that when the smallest salable unit is used as the royalty base, there is necessarily no further constraint on the selection of the base," because "the fundamental concern about skewing the damages horizon . . . does not disappear simply because the smallest salable unit is used." *Id.* at 1327. Nor can EMVR requirements be avoided by claim drafting. In *Lucent*, the claims were drafted so as to cover the use of an entire computer: "A method for use in a computer having a display comprising the steps of displaying on said display a plurality of information fields[.]" *Lucent*, 580 F.3d at 1310-11. The Federal Circuit nonetheless found an EMVR violation, because the inventive features recited in the claim were not "the 'basis for customer demand'" for either "the infringing software" or "the 'infringing' computers loaded with the software." *Id.* at 1336-38.

Idenix has also asserted that *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324 (Fed. Cir. 2015), removed any obligation to satisfy EMVR when "the accused product is a pharmaceutical drug." D.I. 330 at 11-12. Not so. The procedural posture of that case was a district court's ruling that EMVR was per se inapplicable to "**generic** pharmaceutical[s]." *AstraZeneca*, 782 F.3d at 1337. The Federal Circuit disagreed: "While **we do not hold** that the entire market value rule is per se inapplicable in the pharmaceutical context, we concur with the district court that the rule is inapplicable **to the present case**." *Id.* at 1337-38. The accused product in that "present case" was a generic version of a drug, and the patent was directed to everything needed for the generic—a complete recipe. *Id.* at 1328, 1338. Under these facts, the court held that, "[w]hen a patent covers the infringing product as a whole, and the claims recite both conventional elements and unconventional elements, the court must determine how to account for the relative value of the patentee's invention in comparison to the value of the conventional elements recited in the claim, standing alone." *Id.* at 1338.

In contrast, Mr. Carter testified that the '597 patent is **not** directed to everything needed for sofosbuvir: "Idenix would be bringing its patent to the table, **and Gilead would be bringing everything else. Gilead has to provide the drug that cures you, the prodrug that gets the curative drug into the body** . . . ." Tr. 746:12-21. Moreover, even if the '597 patent were directed to all features of sofosbuvir (it is not), Mr. Carter would have still been required to conduct an analysis that "account[s] for the relative value of the patentee's invention in comparison to the value of the conventional elements." *AstraZeneca*, 782 F.3d at 1338. Mr. Carter made no attempt to do so.

Finally, even if Idenix did not have to satisfy EMVR, Mr. Carter's supposed apportionment was inadequate as a matter of law. Mr. Carter simply assumed that Merck and Pharmasset performed an apportionment analysis and that a Gilead/Idenix apportionment would be the same. Tr. 746:10-21. He did not compare the relative value of the patented versus unpatented features in sofosbuvir, against the patented versus unpatented features in the compound at issue in those agreements.[13]

Where a damages award bears no rational relationship to the evidence presented at trial, a district court should order remittitur to the "highest amount the jury could 'properly have awarded based on the relevant evidence.'" *IPPV Enters., LLC v. Echostar Commcn's, Corp.*, 191 F. Supp. 2d 530, 573 (D. Del. 2002). The only admissible theory at trial was Gilead's, showing that damages should be no more than $380 million for a lump sum, fully paid up license. Tr. 796:20-797:5, 812:7-23 (Carter); Tr. 1760:25-1764:14 (Putnam). If the '597 patent is not found invalid, remittitur should be granted.

IV. GILEAD RENEWS ITS REMAINING JMOL MOTIONS AND CLAIM CONSTRUCTION POSITIONS

Gilead renews its JMOL motions that (1) Idenix has failed as a matter of law to prove willful infringement;[14] (2) the '597 patent claims are not entitled to a May 2000 priority date as a matter of

[13] There is further evidence of Mr. Carter's failure to perform proper apportionment. For example, he applied an 11% reduction to the adjusted net sales of Harvoni in order to remove the ledipasvir component from the damages base, yet he provided no explanation for how he reached this number. Tr. at 750:7-23 (Carter). He also applied the same 10% royalty rate regardless of the number or nature of patents that were part of the hypothetical negotiation. Tr. 790:7-791:6 (Carter).

law; and (3) the asserted claims of the '597 patent are invalid as a matter of law based on Merck's work. Gilead submits these motions on its prior briefing and the record. *E.g.*, D.I. 509; Tr. 2029.[15]

Gilead also respectfully renews its request that Court adopt Gilead's claim construction positions and enter judgment of non-infringement, based on its previous briefing on these matters.

V. IN THE ALTERNATIVE, GILEAD REQUESTS A NEW TRIAL

To the extent JMOL is not granted, Gilead requests a new trial on all issues pursuant to Federal Rule of Civil Procedure 59. Among other things, "the jury's verdict is against the clear weight of the evidence," and Idenix's conduct at trial "unfairly influenced the verdict."[16] *Masimo Corp. v. Philips Elec. N. Am. Corp.*, 9-cv-80-LPS, 2015 WL 2379485, at *3 (D. Del. May 18, 2015).

VI. ANY ONGOING ROYALTY CLAIM SHOULD BE SEVERED AND STAYED

Any ongoing royalty would be complex and would include the new product Epclusa not presented to the jury, which combines separate drug components, only one of which is a 2' methyl up compound. New findings of fact are needed. Gilead requests the Court sever any ongoing royalty claim into a separate suit under Rule 21 and stay it until after conclusion of the appeal in this case.

CONCLUSION

Gilead requests that the Court grant it judgment as a matter of law, or in the alternative a new trial, on all issues. Gilead further requests that any ongoing royalty claim be severed and stayed.

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[14] Among other reasons, willfulness should not have been presented to the jury especially in light of the stipulation of infringement, the fact there was no substantial evidence of willfulness after issuance of the patent or the start of any infringement, all alleged infringement occurred after initiation of suit, and Gilead had a good faith belief of non-infringement and invalidity as evidence in this case and at trial, including via the testimony of Drs. Otto, Sophia and Mr. Clark, and the fact willfulness should not be a jury issue given § 284's text committing enhancement to "the court."

[15] Gilead preserves its objections to (1) not being permitted to present all defenses, *e.g.*, its good faith belief it was not infringing a valid patent; (2) the Court's instructions and verdict form, to the extent they differ from Gilead's proposals; (3) all adverse evidentiary rulings. D.I. 138, 380.

[16] This conduct includes the presentation of legally insufficient testimony, the fact that willfulness was presented to the jury at all despite § 284's requirement that only "the court" resolve issues related to enhancement, and inappropriate argument on claims that were never pleaded, including "theft," breach of confidentiality, copying, and a failure to compensate Pharmasset employees. Tr. 210:7-211:25, 245:14-23; Tr. 2105:13-2108:16. Idenix's focus on alleged misconduct tainted the jury's consideration of the claims actually at issue, necessitating a new trial on liability and damages.

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